UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,466	03/26/2004	Ming H. Wu	MEM-0004	1783

23413 7590 02/17/2009

CANTOR COLBURN, LLP
20 Church Street
22nd Floor
Hartford, CT 06103

EXAMINER	
HORNBERGER, JENNIFER LEA	

ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
02/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

Office Action Summary	Application No.	Applicant(s)	
	10/811,466	WU ET AL.	
	Examiner	Art Unit	
	JENNIFER L. HORNBERGER	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-22, and 25-43* is/are pending in the application.

4a) Of the above claim(s) *22, 25, 28, and 31-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-21,26,27,29, and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/04/2008 has been entered.

2. Claims 1, 6-22, and 25-43 are pending. Claims 22, 25, 28, and 31-43 are currently withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 6, 10-14, and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eum et al. (US 2002/0177899) in view of Hossainy (US 6,153,252).

Regarding claim 1, Eum al. disclose a medical device comprising: a nickel-titanium based shape memory alloy having a reverse martensitic transformation start temperature (A_s) of about 10 degrees Celsius to about 20 degrees Celsius; and a transformation start temperature of (A_f) of about 30 degrees Celsius plus or minus 5 degrees Celsius (paragraph 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum ranges for both the transformation start and transformation finish temperatures, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

In re Aller, 105 USPQ 233. Eum et al. fail to disclose a drug coating comprising a polymeric resin and one or more biologically active agents. Hossainy et al. disclose coating a nickel-titanium alloy stent with a drug coating comprising a polymeric resin and one or more biologically active agents (col. 7, ln. 1-4). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have coated the stent of Eum et al. with the drug coating comprising a biologically active agent as taught by Hossainy et al. to deliver drugs locally to the vessel for example to prevent thrombosis and restenosis (col. 1, ln. 12-24).

Regarding claim 6, Eum et al. disclose the nickel-titanium based alloy is a binary nickel-titanium alloy, nickel-titanium-niobium alloy, nickel-titanium-copper alloy, nickel-titanium-iron alloy, nickel-titanium-hafnium alloy, nickel-titanium-palladium alloy, nickel-titanium-gold alloy, nickel-titanium-platinum alloy, or comprising at least one of the foregoing nickel-titanium based alloys (paragraph 10).

Regarding claim 10, Hossainy et al. fail to disclose the glass transition temperature less than or equal to a reverse martensitic transformation start temperature of the shape memory alloy. However, Hossainy et al. discloses that the polymeric coating should not crack during the expansion of the stent (col. 5, ln. 39-51). Therefore, one of ordinary skill in the art would have provided a polymeric resin having a glass transition temperature less than or equal to the reverse martensitic transformation start temperature so that the coating would not crack during expansion.

Regarding claim 11, Hossainy et al. disclose the polymeric resin is a thermoplastic resin, thermosetting resin or a blend of a thermoplastic resin with a thermosetting resin (col. 5, ln. 39-51).

Regarding claim 12, Hossainy et al. disclose thermoplastic resin is polyacetal, polyacrylic, polycarbonate, polystyrene, polyethylene, polypropylene, polyethylene

terephthalate, polybutylene terephthalate, polyamide, polyamideimide, polybenzimidazole, polybenzoxazole, polybenzothiazole, polyoxadiazole, polythiazole, polyquinoxaline, polyimidazopyrrolone, polyarylate, polyurethane, polyarylsulfone, polyethersulfone, polyphenylene sulfide, polyvinyl chloride, polysulfone, polyetherimide, polytetrafluoroethylene, fluorinated ethylene propylene, perfluoroalkoxy polymer, polychlorotrifluoroethylene, polyvinylidene fluoride, polyvinyl fluoride, polyetherketone, polyether etherketone, polyether ketone or a combination comprising at least one of the foregoing thermoplastic resins (col. 5, ln. 6-37).

Regarding claim 13, Hossainy et al. disclose the thermosetting resin is a polyurethane, natural rubber, synthetic rubber, epoxy, phenolic, polyester, polyamide, silicone, or a combinations comprising at least one of the foregoing thermosetting resin (col. 5, ln. 6-37).

Regarding claim 14, Hossainy et al. discloses the drug coating comprises an amount of about .001 weight percent to about 70 weight percent of the biologically active agent based on total weight of the drug coating (col. 9, ln. 20-25). Hossainy et al. disclose the claimed invention except for the drug coating comprising an amount of about 5 weight percent to about 90 weight percent of the biologically active agent based on the total weight of the drug coating. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum amount of the biologically active agent, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 16, Hossainy et al. disclose the biologically active agents are dispersed within the polymeric resin (col. 8, ln. 36-67).

Regarding claim 17, Hossainy et al. disclose biologically active agents encapsulated between layers of polymeric resins (col. 20, ln. 3-29; Fig. 2).

Regarding claim 18, Hossainy et al. disclose the polymeric resin is a biodegradable polymer having different degradability rates in order to control the release of drugs at various rates and times or to release multiple drugs with different pharmaceutical behaviors (col. 7, ln. 17-55).

Regarding claim 19, Hossainy et al. disclose wherein the biodegradable polymer is a polylactic-glycolic acid, poly-caprolactone, copolymer of polylactic-glycolic acid and poly-caprolactone, polyhydroxy-butyrate-valerate, polyorthoester, polyethyleneoxide-butylene terephthalate, poly-D,L-lactic acid-p-dioxanone-polyethylene glycol block copolymer or a combination comprising at least one of the foregoing biodegradable polymers (col. 4, ln. 15-67).

Regarding claims 20 and 21, Eum et al. disclose the implantable device is a stent, bone staple, a vena cava filter, a suture, or an anchor-like mechanism (paragraph 1).

5. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eum et al. (US 2002/0177899) and Hossainy et al. (US 6,153,252) as applied to claim 1 above, and further in view of Simpson et al. (US 4,770,725).

Regarding claims 7 and 9, Eum et al. discloses the claimed invention except for the nickel-titanium based alloy containing niobium. Simpson et al. disclose a shape memory alloy consisting of nickel, titanium, and niobium (see abstract) . It would have been obvious to one of ordinary skill to substitute the shape memory alloy of Eum et al. with shape memory alloy of Simpson et al. to provide self-expanding property to a stent. Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention. As to the compositions of the nickel-titanium-niobium allow, it would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum nickel and niobium compositions, since it has been held that where the general conditions of a claim are disclosed

in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eum et al. (US 2002/0177899) and Hossainy (US 6,153,252) as applied to claim 1 above, and further in view of Zscheeg (US 6,911,041). Eum et al. disclose a Nitinol stent but fail to disclose the weight percent of nickel based on the total composition of the alloy. Zscheeg disclose that it is well known in the art that Nitinol comprising 54.5 to 57 % weight percent nickel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum weight percent of nickel, since it has been held that discovering the optimum value of a result effect variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

7. Claims 1 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eum et al. (US 2002/0177899) in view of Le Moel et al. (US 6,517,858).

Regarding claim 1, Eum al. disclose a medical device comprising: a nickel-titanium based shape memory alloy having a reverse martensitic transformation start temperature (A_s) of about 10 degrees Celsius to about 20 degrees Celsius; and a transformation start temperature of (A_f) of about 30 degrees Celsius plus or minus 5 degrees Celsius (paragraph 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum ranges for both the transformation start and transformation finish temperatures, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Eum et al. fail to disclose a drug coating comprising a polymeric resin and one or more biologically active agents. Le Moel et al. disclose coating a metallic stent with a drug coating comprising a polymeric resin and one or more biologically active agents (see

abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have coated the stent of Eum et al. with the drug coating comprising a biologically active agent as taught by Le Moel et al. to deliver drugs locally to the vessel for example to prevent thrombosis and restenosis.

Regarding claim 15, Le Moel et al. disclose the biologically active agents are copolymerized with the polymeric resin (col. 5, ln. 52-60 and claim 20).

8. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eum et al. (US 2002/0177899) in view of Zscheeg (US 6,911,041). Eum al. disclose stent manufactured from a nickel-titanium based shape memory alloy having a reverse martensitic transformation start temperature (A_s) of about 10 degrees Celsius to about 20 degrees Celsius (paragraph 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum range for both the transformation start, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Eum et al. disclose a Nitinol stent but fail to disclose the weight percent of nickel based on the total composition of the alloy. Zscheeg disclose that it is well known in the art that Nitinol comprising 54.5 to 57 % weight percent nickel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum weight percent of nickel, since it has been held that discovering the optimum value of a result effect variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eum et al. (US 2002/0177899) and Zscheeg (US 6,911,041) as applied to claim 26 above, and further in view of Hossainy (US 6,153,252). Eum et al. fail to disclose a drug coating. Hossainy et al. disclose

coating a nickel-titanium alloy stent with a drug coating comprising a polymeric resin and one or more biologically active agents (col. 7, ln. 1-4). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have coated the stent of Eum et al. with the drug coating comprising a biologically active agent as taught by Hossainy et al. to deliver drugs locally to the vessel for example to prevent thrombosis and restenosis (col. 1, ln. 12-24).

10. Claim 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eum et al. (US 2002/0177899) in view of Simpson et al. (US 4,770,725). Eum et al. disclose a stent comprising a nickel titanium based shape memory alloy, wherein the alloy has a reverse martensitic transformation start temperature of about 10 degrees Celsius to about 15 degrees Celsius (paragraph 10). Simpson et al. disclose a nickel-titanium-niobium alloy (see abstract). It would have been obvious to one of ordinary skill to substitute the shape memory alloy of Eum et al. with shape memory alloy of Simpson et al. to provide self-expanding property to a stent. Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention. As to the compositions of the nickel-titanium-niobium allow, it would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum nickel and niobium compositions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

11. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eum et al. (US 2002/0177899) in view of Simpson et al. (US 4,770,725), and further in view of Hossainy et al. Eum et al. fails to disclose the stent is coated with one or more drug coatings having biologically active agents. Hossainy et al. disclose coating a nickel-titanium alloy stent with a drug coating comprising one or more biologically active agents (col. 7, ln. 1-4). Therefore, it would have been

obvious to one of ordinary skill in the art at the time of the invention to have coated the stent of Eum et al. with a drug coating comprising a biologically active agent as taught by Hossainy et al. to deliver drugs locally to the vessel for example to prevent thrombosis and restenosis (col. 1, ln. 12-24).

Response to Arguments

12. Applicant's arguments filed 12/04/2008 have been fully considered but they are not persuasive. Applicant argues that Eum et al. refers to reverse martensitic transformation start temperature in paragraph 11 using the notation T_{ms}. The examiner respectfully disagrees and submits that the reverse martensitic transformation start temperature is not the same as the martensitic transformation start temperature (T_{ms}) as referred to by Eum in paragraph 11. It is well known in the art that "reverse martensitic transformation start temperature" is synonymous with austenite start transformation temperature. See paragraph 31 of Yamauchi et al. (US 2005/0209683), paragraph 3 of Holemans et al (US 2004/0221614), paragraph 28 of Bown et al (US 2008/0194994), and col. 1, ln. 20-30 of Suzuki (US 4,407,776). Therefore, the examiner maintains the position that Eum et al. disclose the austenite start temperature (or reverse martensitic transformation start temperature) of about 10 to 15 degrees Celsius (paragraph 10). If applicant intends for "reverse martensitic transformation temperature" to have a meaning other than the definition that is well known in the art, the applicant's definition must be clearly defined in the specification.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
02/09/2009

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734